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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/050,249	OKAMURA ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93,99,100,104,106,107,116,121 and 122* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93,99,100,104,106,107,116,121 and 122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 04 May 2010 is acknowledged and entered. Following the amendment, claims 108, 117 and 120 are canceled, claims 121 and 122 are amended.

Currently, claims 93, 99, 100, 104, 106, 107, 116, 121 and 122 are pending and under consideration.

Withdrawal of Objections and Rejections:

The new matter rejection of claims 121 and 122 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93, 99, 100, 104, 106, 107 and 116 remain rejected, and claims 121 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993), and further in view of Campbell, A. (Laboratory Techniques in Biochemistry And

Molecular Biology, Volume 13, Chapter 1, pages 1-33, 1984), for the reasons of record set forth in the last Office Action mailed on 2/4/10, at pages 5-6.

Applicants argument filed on 04 May 2010 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 12-13 of the response, the applicant argues that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to make the claimed antibody since Nakamura did not succeed in isolating mouse IL-18/IGIF; that as Campbell states, obtaining the "macromolecule" as antigen with relatively high purity and in relatively large amounts is also indispensable for preparing monoclonal antibodies to the "macromolecule", in this regard, Nakamura did not obtain either mouse IL-18/IGIF producing cells or mouse IL-18/IGIF with relatively high purity and in a relatively large amount; and that Applicants therefore believe that it would have been difficult for a person of ordinary skill in the art at the time the presently claimed invention was made to prepare mouse IL-18/IGIF by recombinant DNA techniques because the cells from which to prepare the mRNA encoding the macromolecule had not even been identified. This argument is not persuasive because although Nakamura did not obtain the IL-18/IGIF producing cells or mouse IL-18/IGIF with relatively high purity and in a relatively large amount, it does not mean that such was not doable one of ordinary skill in the art at the time the invention was made. Nakamura identified the serum IGIF, demonstrated its functional activity, and purified it to a certain degree; and the state of the recombinant technology was high at the time the invention was made, and isolating a gene encoding a serum protein or identifying a cell source producing the protein was not unprecedented. Thus, a person of ordinary skill in the art would be able to identify the cell producing the IGIF or the gene encoding the IGIF based on the teachings of Nakamura and readily available techniques in the relevant field in the absence to the contrary. Further, there is no evidence that either Nakamura or others in the field had tried and failed repeatedly to identify the cell producing the IGIF or the gene encoding the IGIF. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. In the absence of evidence, applicants argument regarding the technical difficulties in identifying the cell source and isolating the gene is unsound.

At pages 13-15 of the response, applicants present previous argument that Nakamura's factor is different from that of Okamura in MW and activity in the presence of DTT. This argument is not persuasive for the reasons of record.

With respect to claims 121 and 122, Campbell also teaches that the earliest most successful preparative use of monoclonal antibodies was in the purification of alpha interferon, and it should be possible to immobilize any monoclonal antibody on an affinity column and use it to obtain large quantities of the required antigen from a crude mixture (page 25, last paragraph). The reference does not teach a kit containing immobilized antibody. However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing said antibody immobilized on a matrix such as an affinity column, as such kit would facilitate its application, commercial distribution, and research uses. Packing such a kit is old and well known in the art.

Further, Applicants made repeated argument based on the declaration of Dr. Okamura under 37 CFR 1.132 filed on 9/24/09.

At page 6 of the response, the applicant argues that more weight should be given to Dr. Okamura's declaration because Dr. Okamura, who is a co-author of both the cited and applied Nakamura reference and the latter published Okamura reference used by the examiner as evidence, provides insight into what the authors of these references were thinking at that time. This argument is not persuasive because patentability does not rest on thoughts, rather, patentability determination is based on fact and evidence.

At pages 7-8 of the response, the applicant argues that the present inventors finally found and identified the cells which are capable of producing mouse IL-18/IGIF consisting of the amino acid sequence of SEQ ID NO:2, a finding which was neither disclosed nor suggested by Nakamura, and the present inventors further succeeded in obtaining mouse IL-18/IGIF, using mRNA isolated from these cells and recombinant DNA techniques, in an amount sufficient for preparing monoclonal antibodies against mouse IL-18/IGIF; that in his declaration, Dr. Okamura stated "the above finding was the breakthrough or the key to success for obtaining the monoclonal antibody of the instant application"; and that Nakamura cannot be considered to disclose any method for successfully purifying and isolating Nakamura's factor. This argument

is not persuasive because while identifying the cells producing mouse IL-18/IGIF, obtaining mouse IL-18/IGIF using recombinant DNA techniques in an amount sufficient for preparing monoclonal antibodies was the key to success for obtaining said monoclonal antibody, it does not render the instant invention novel because the invention is directed to a product, an antibody to a protein disclosed by the prior art (not a method of making the product); and the general technology of gene cloning or recombinant DNA techniques were well established and readily available. Further, as addressed above, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

At pages 9-11 of the response, applicants made argument based on the Timmann reference cited by the examiner in the last Office Action, that Timmann's "Factor H" is present in human serum in quite a high concentration of about 40mg/l, by contrast, mouse serum contains only about 0.0025 to 0.0050 mg/l; that applicants believe that Timmann were successful in determining the base sequence encoding "Factor H" because they were already aware that human liver cells are the source cells for producing "Factor H"; and that the method disclosed by Timmann would not have been applicable to the isolation of mouse IL-18/IGIF. This argument is not persuasive because the instant rejection is not based on the Timmann reference, and it is merely used as an example showing various techniques in gene cloning were readily available at the time the invention was made.

Conclusion:

No claim is allowable.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

/Dong Jiang/
Primary Examiner, Art Unit 1646
7/8/10